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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,725	04/23/2001	Hans-Werner Heinrich	101195-44	4120

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EXAMINER	
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ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/786,725	HEINRICH ET AL.	
	Examiner	Art Unit	
	JAMES L. GRUN	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6-15 and 17-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,6-15 and 17-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/2/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02 March 2010 has been entered. The new claims filed 02 March 2010 as claims 23 and 23 were renumbered under 37 CFR § 1.126 as claims 23 and 24, respectively. Claims 23 and 24 are newly added. Claims 1, 3, 6-15, and 17-24 remain in the case.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Claims 1, 3, and 17-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention as is now claimed.

Applicant teaches the immunization of animals to obtain specific antibodies for use in diagnostic tests of human elastase and kits therefor. Applicant does not describe or enable any method or kit in which the patient is administered elastase peptides to obtain antibodies or a method to determine overall elastase content by detecting the "existence" of antigen-antibody reactions in an immunized patient as now claimed. Applicant is requested to direct the Examiner's attention to specific passages where support for these newly recited limitations can be found in the specification as filed or is required to delete the new matter.

Claims 1, 3, 6-11, and 17-24 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record, that the specification contains subject matter which was not described in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. For the reasons of record, the issue is whether the disclosure describes and supports the ability of the recited peptides to elicit antibodies that bind singly, or in combination, and function for determination of elastase isoforms I, II, and III in a body fluid sample.

As set forth previously, applicant exemplifies only polyclonal antibodies to particular peptides and provides no description or guidance to any single antibody or monospecific species, or pair thereof as now claimed, which functions in the invention to bind to the 5 known, or 4 human pancreas-produced, elastase iso-enzymes. The exemplified antibodies bind to the peptides used as immunogens or to elastase in a Western blot after sodium dodecyl sulfate

polyacrylamide gel electrophoresis (SDS-PAGE). Applicant states that "not every antibody detects all isoforms" in this assay (see page 10), appearing to imply that some antibodies (or combinations?) bind all isoforms. However, there is nothing in the specification to indicate which, if any, of the anti-peptide antibodies bind to all isoforms so that one could practice the invention as desired and claimed to detect all isoforms with a single antibody, or with a pair as now claimed, absent further unguided unpredictable experimentation to complete applicant's suggested invention. As set forth, adequate written description requires more than a mere statement that a product is part of the invention, more than a reference to a potential method of isolating it, and more than a generic statement which defines a genus of products by only their functional activity. As set forth, the product itself is required as well as recitation of a representative number of products falling within the scope of a claimed genus. Moreover, as set forth, all possible analogs of a product are not enabled by a disclosure wherein the characteristics of the analogs are unpredictable. As set forth, a patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. As set forth, absent further written description and guidance from applicant, one would have no assurance of successfully obtaining appropriate functional reagents and predictably performing the method as suggested by applicant. For the reasons of record, and as summarized above, applicant has not described or enabled any antibody which functions **singly** or in a pair as claimed.

For reasons of record, applicant also provides no guidance for usable combinations. In this regard, as set forth, some of the peptides suggested for use by applicant would be expected to elicit antibodies that bind to an isoform which corresponds to porcine elastase, which is not

expressed in the human pancreas (see e.g. Tani et al., page 1231, and Fig. 9), and which would complicate the assay in certain patient populations, such as those patients receiving enzyme replacement therapy with animal, such as porcine, pancreatic enzymes (see Schneider et al. in this regard). Moreover, as set forth, one would not be able to perform a sandwich assay with combinations that do not bind to epitopes found at two sites on the same enzyme molecule, e.g. a combination would not function in the invention in which one antibody binds elastase I as known to the art (i.e. elastases IIIA and/or IIIB, see e.g. Tani et al.) and the other binds to an epitope on the un-expressed isoform (i.e. elastase I, see e.g. Tani et al.) which does not cross-react with elastase I (i.e. elastases IIIA and IIIB, see e.g. Tani et al.), combinations suggested by applicant's disclosure.

Moreover, the abstract of Weiss et al. teaches that applicant was not in possession of the invention as claimed in 2006 because antibodies produced by the instant assignee (BIOSERV) and used in assays of stool elastase are clearly shown not to bind all isoforms of elastase. Further experimentation is taught as required by the reference for one to assess the specific differences and prognostic value of elastase isoforms in the assessment of exocrine pancreatic insufficiency. These results contrast with the results of Schneider et al. in which previous antibodies produced by the instant assignee (BIOSERV) and used in assays of stool elastase in 2005 are suggested to bind to porcine enzymes. Again, functional combinations are not clearly disclosed by applicant so that one would know without question what combinations predictably functioned in applicant's suggested invention when the application was originally filed.

As set forth previously, applicant exemplifies only polyclonal antibodies to particular peptides and provides no description or guidance to any antibodies or combination of antibodies

capable of predictable binding to any or all of the elastase enzyme isoforms as found in stool or body fluid samples, because only binding to proteins in Western blots, i.e. after SDS denaturation, is specifically exemplified. One could not predict the ability of any of the antibodies to the suggested peptides to bind to non-denatured protein as found in a fluid sample from a patient. As set forth, adequate written description requires more than a mere statement that a product is part of the invention, more than a reference to a potential method of isolating it, and more than a generic statement which defines a genus of products by only their functional activity. As set forth, the product itself is required as well as recitation of a representative number of products falling within the scope of a claimed genus. Moreover, as set forth, all possible analogs of a product are not enabled by a disclosure wherein the characteristics of the analogs are unpredictable. As set forth, a patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. As set forth, absent further written description and guidance from applicant, one would have no assurance of successfully obtaining appropriate functional antibody reagents and predictably performing the method as suggested by applicant.

Applicant's arguments filed 02 March 2010 have been fully considered but they are not deemed to be persuasive.

Applicant urges that the specification teaches monoclonal antibodies. This is not found persuasive for the extensive reasons of record, in particular that applicant does not teach a single antibody, or a pair of antibodies as is now claimed, that bind to elastase isoenzymes I (not expressed in the human pancreas), II (i.e. IIA and IIB), and III (i.e. IIIA and IIIB) and functions in the invention for determination of all.

Applicant urges that a specific combination of antibodies that would function in the invention would be apparent to one skilled in the art. This is not found persuasive for the extensive reasons of record and because, as set forth, "there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement."

Applicant urges that the abstracts of Weiss et al. and Keim et al. prove that one in the art could practice the invention as claimed. This is not found persuasive for the reasons of record that the abstract of Weiss et al. teaches that applicant was not in possession of the invention as claimed in 2006 because antibodies produced by the instant assignee (BIOSERV) and used in assays of stool elastase are clearly shown not to bind all isoforms of elastase, the antibodies bound only to elastase III isoforms although elastase II is produced by the pancreas. Notwithstanding applicant's assertions to the contrary, the abstract of Keim et al. teaches nothing with regard to the specificity of the antibodies in the BIOSERV kit for multiple isoforms of elastase.

The assertions in the declaration of Dr. Hans-Werner Heinrich were not found persuasive for the extensive reasons of record regarding the lack of sufficient description or enablement of the invention as instantly claimed. The assertions regarding enzyme fragmentation were not found persuasive because they are at odds with the disclosure of the extraordinary stability of the enzyme during passage through the intestines (see e.g. Specification, page 2). The assertions regarding detection of elastases I, II, and III by the invention as claimed were not found persuasive because they are not supported by any evidence of record commensurate in scope

with the invention as claimed as set forth in the reasons of record, such as in view of the abstract of Weiss et al. The assertion regarding the exclusion of cross-reactions by the invention as claimed were not found persuasive for the reasons of record, such as in view of the results of Schneider et al. Again, functional combinations are not clearly disclosed by applicant so that one would know without question what combinations predictably functioned in applicant's suggested invention when the application was originally filed.

Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 10, 18, and 20-24 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 and claims dependent thereupon, the interrelationships of the components and steps of the method are entirely unclear to the point that one would not know what is determined or how to perform the method. As claimed, the method apparently involves immunizing a patient with at least peptide pairs to elicit antibodies that bind to elastases I, II, **or** III for the intended use of determining overall content of elastases I, II, **and** III presumably by merely detecting the existence and quantity of an antigen-antibody complex in some undefined manner. It is not clear if applicant intends some determination of reaction in the patient as being encompassed. There is no connection between inducing antibodies in the patient and any assay

performed on a sample from the patient. There is no connection between the antibodies induced in the patient and the antibodies obtained from animals in claim 3. There is no connection between the synthetic peptides in claim 20 to the complete elastases in claim 3 or if the peptides are to be considered as sub-units. In claim 20, it is believed --myeloma-- was intended. The connections between claims 23 and 24, reciting individual elastases, to the method of claim 1 in which overall content of elastases I, II, **and** III is to be determined are entirely unclear.

In claim 1 and claims dependent thereupon, improper Markush language is used to claim the members of the group. The alternatives "selected from...or" or "selected from the group consisting of...and" are acceptable.

In claim 23, improper Markush language is used to claim the members of the group. The alternatives "selected from...or" or "selected from the group consisting of...and" are acceptable.

Claims 10 and 22 are duplicative, each claiming identical subject matter.

In claim 18, --The-- immunological test kits should be recited for proper reference to the previously recited claim components.

Applicant's arguments filed 02 March 2010 have been fully considered but they are not deemed to be persuasive.

Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-8, 10, and 22 are rejected under 35 U.S.C. § 102(b) as being anticipated by Sziegoleit et al. (Clin. Biochem. 22: 79, 1989) in light of the instant disclosure for reasons of record repeated below for convenience.

Sziegoleit et al. teach a sandwich enzyme-linked immunosorbent assay for diagnosis of pancreatitis or pancreatic cancer by determining pancreatic elastase 1 using polyclonal antibodies. The antibodies were elicited in several animal species, including rabbits, with complete elastase 1 which, in light of the instant disclosure, comprises the peptides in their entirety (i.e. an immunogenic portion) as instantly claimed.

Claims 6-8, 10, 11, and 22 are rejected under 35 U.S.C. § 102(b) as being anticipated by Scheefers et al. (U.S. Pat. No. 5,622,837) in light of the instant disclosure for reasons of record repeated below for convenience.

Scheefers et al. (U.S. Pat. No. 5,622,837) teach determinations of pancreatic elastase 1 in serum and stool samples as indicative of pancreatic disease. The reference teaches determinations with sandwich immunoassays involving antibodies, preferably monoclonal, elicited to different epitopes of the protein, including the use of antibodies specific for particular epitopes therein elicited by immunization with purified enzyme or fragments thereof, as a sensitive alternative to radioimmunoassay. In light of the instant disclosure, highly purified pancreatic elastase 1, as taught in the reference as an immunogen (see e.g. ¶ bridging col. 2-3) for elicitation of the antibodies, comprises the peptides in their entirety (i.e. an immunogenic portion) as instantly claimed. The reagents for the method can be incorporated into a kit.

Applicant's arguments filed 02 March 2010 have been fully considered but they are not deemed to be persuasive.

Notwithstanding applicant's assertions to the contrary, there is nothing found in the declaration of Dr. Hans-Werner Heinrich that distinguishes the invention as instantly claimed in the rejected claims from the antibodies and methods taught in the references.

In the declaration and arguments drawn thereto, applicant now urges that the antibodies of the prior art are specific for many different epitopes of elastases IIIA and IIIB, bind other enzymes, and are not appropriate for diagnosis. These are not found persuasive for the reasons of record and because applicant has provided no *factual* evidence of a difference for the reagents as instantly claimed and those as used in the references. As set forth, Sziegoleit et al. teach elicitation of polyclonal antibodies to purified enzyme and Scheefers et al. teach elicitation of both polyclonal and monoclonal antibodies to purified enzyme and fragments thereof, not only to the suggested antigen/immunogen as instantly excluded, for use in sandwich enzyme-linked immunosorbent assay for diagnosis of pancreatic diseases. As set forth, the enzyme preparation would inherently be a mixture of at least the elastase I isoforms (i.e. elastases IIIA and IIIB), comprising the peptides as instantly claimed, and polyclonal antibodies elicited thereto would inherently bind to the isoforms and cross-react with similar epitopes as found in elastase II. Moreover, the teaching of a preferred peptide does not serve to teach away from any other fragment of the enzyme as taught for use in Scheefers et al. (see e.g. col. 2). As set forth, the Patent and Trademark Office does not have the facilities and resources to provide the *factual* evidence needed in order to establish that there is a difference, in the first place, between the reagents of the prior art and those instantly disclosed and, that if there is such a difference, that

such a difference would have been considered unexpected, i.e. unobvious, by one of ordinary skill in the art. The burden is upon applicant to present such factual evidence. See e.g. In re Best (195 USPQ 430 (CCPA 1977)) or Ex parte Phillips (28 USPQ2d 1302 (BPAI 1993)). Applicant's arguments have not met this burden.

Applicant urges that the claimed invention is already practically used as evidenced by the abstract of Weiss et al. (published variously in: J. Ped. Gastroenterol. Nut.; Pancreatology; and Pancreas). This is not found persuasive because the showing in the abstract of Weiss et al. teaches that applicant was not in possession of the invention as claimed because antibodies produced by the instant assignee (BIOSERV) and used in assays of stool elastase are clearly shown not to bind all isoforms of elastase although elastase II might be expected in the samples.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> (c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1, 3, 6-15, and 17-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Scheefers et al. (U.S. Pat. No. 5,622,837), Tani et al. (J. Biol. Chem. 263: 1231, 1988), and Harlow et al.

The teachings of Scheefers et al. are as set forth above. In contrast to the invention as instantly disclosed and/or claimed, the reference does not teach the use of particular fragments of elastase as instantly disclosed and/or claimed.

Tani et al. teach the amino acid sequences encoded by human elastase genes (see Fig. 9). The reference teaches that the sequence identified therein as elastase I is not expressed in human adult pancreas (see page 1231, col. 2) and that the sequences identified therein as elastase III are human elastase I as known to the art (see page 1237, col. 2).

Harlow et al. teach that, once the amino acid and/or nucleic acid sequences of a protein are known, it is routine and conventional in the art to elicit antibodies to peptides and/or fusion proteins derived from the protein and/or to prepare a bank of site-specific monoclonal antibodies for use (pages 72-77). Harlow et al. teach rationales for the selection of synthetic peptides as immunogens and suggest the carboxyl-terminal or amino-terminal peptide sequences or internal hydrophilic regions as desirable starting peptide immunogens (page 76).

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have selected peptide sequences from the elastase sequences disclosed in Tani et al. for use in the methods of Scheefers et al. because Scheefers et al. teach the use of purified enzyme, or fragments or peptides thereof, for elicitation of antibodies for use in their pancreatic disease diagnosis methods and Harlow et al. teach that it is conventional in the art to elicit antibodies to peptides derived from a known sequence for use. One would have been

motivated to have selected dissimilar sequences from amongst the elastase isoforms to elicit antibodies specific for the isoforms or to have selected similar sequences from amongst the elastase isoforms to elicit antibodies specific for elastase, generally, for use in Scheefers et al., as modified, because such selection is routine in the art and well within the skill of an ordinary practitioner from the sequence comparisons presented in Tani et al.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Applicant's arguments with respect to the claims filed 02 March 2010 have been fully considered but are moot in view of the new ground(s) of rejection.

The art made of record and not relied upon is considered pertinent to applicant's disclosure.

Geokas et al. (J. Biol. Chem. 252: 61, 1977) teach an immunoassay for human elastase II in human serum and the elevation of the enzyme therein in individuals with acute pancreatic inflammation (see paged 66, col. 2).

Schneider et al. (Clin. Chem. 51: 1052, 2005) teach complications if antibodies in a human elastase detection assay bind to porcine elastases.

The abstract of Weiss et al. (published variously in: J. Ped. Gastroenterol. Nut.; Pancreatology; and Pancreas) teaches that applicant was not in possession of the invention as claimed in 2006 because antibodies produced by the instant assignee (BIOSERV) and used in assays of stool elastase are clearly shown not to bind all isoforms of elastase. Further

experimentation is taught as required by the reference for one to assess the specific differences and prognostic value of elastase isoforms in the assessment of exocrine pancreatic insufficiency.

Stein et al. (Clin. Chem. 42: 222, 1996) teach the clinical evaluation of the fecal elastase assay of Scheefers et al. (US 5,622,837).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, SPE, can be contacted at (571) 272-0806.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J. L. G./
James L. Grun, Ph.D.
Examiner, Art Unit 1641
March 25, 2010

/Shafiqul Haq/
Primary Examiner, Art Unit 1641